each repacked batch and of each batch of another drug manufactured from such drug.

§ 431.17 Request to provide for certification of an antibiotic drug.

A request under section 507 of the Federal Food, Drug, and Cosmetic Act to provide for certification of an antibiotic drug is required to comply with the procedures and meet the requirements applicable to the submission to the Food and Drug Administration and review by the agency of applications and abbreviated applications, and amendments and supplements to them, under part 314 of this chapter.

[50 FR 7516, Feb. 22, 1985]

§ 431.20 Disposition of outdated drugs.

When certification becomes invalid because the expiration date is passed, such articles should not be disposed of for drug use either through commercial or charitable channels unless the articles have been assayed to establish potency and recertified.

Subpart B—Administrative Procedures

§ 431.50 Forms for certification or exemption of antibiotic drugs.

The following forms which must be supplied in connection with certain certification or exemption procedures for antibiotic drugs may be obtained from the Product Surveillance Branch (HFD–333), Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

Form
1 Application for exemption for storage.
2 Application for exemption for processing.
3 Application for exemption for labeling.
4 Application for exemption for manufacturing use.
7 Request for check tests and assays or certification of a batch of _____(the blank to be filled in with the name of the antibiotic drug).
8 Application for exemption for repacking.
9 Request for supplemental certification of a batch of an antibiotic drug.

[39 FR 18934, May 30, 1974, as amended at 40 FR 28052, July 3, 1975; 41 FR 10886, Mar. 15, 1976; 50 FR 7516, Feb. 22, 1985; 50 FR 8997, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990]

§ 431.51 Suspension of certification service.

When the Commissioner finds that a person has:

(a) Obtained or attempted to obtain a certificate through fraud or through misrepresentation or concealment of a material fact; or

(b) Falsified the records required to be kept by § 431.61; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to take an inventory of stocks on hand, or otherwise to check the correctness of such records as required by § 431.61; or

(d) Failed to establish a system for maintaining the records required by § 314.81 of this chapter or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of that section, or has refused to permit access to, or copying, or verification of such records or reports; or

(e) Failed to conform to the requirements of good manufacturing practice prescribed by parts 210, 211, 225, 226 and 229 of this chapter;

the Commissioner will immediately suspend service to such person under the regulations in this chapter. Upon request a hearing will be granted to such person to show cause why such service should be resumed.

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 55 FR 11582, Mar. 29, 1990]

§ 431.52 Hearings.

Any person who contests the suspension of certification service under § 431.51 shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[41 FR 48267, Nov. 2, 1976, as amended at 42 FR 15675, Mar. 22, 1977]

§ 431.53 Fees.

(a) Fees for the services rendered under the regulations in this chapter shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this chapter, shall be $114 for each batch submitted, plus the sum of the fees for all individual tests required for certification of each batch. The minimum tests for each batch shall be those prescribed in the section relating specifically to such drug.

(1) The fee schedule for specific tests required for antibiotic drug certification is as follows:

CHARGEABLE FEE PER TEST

Arquad content	$20
Benzylpenicilloyl content	32
Bleomycin	1,291
Butanol content	52
Candicidin potency (special turbidimetric)	85
Capreomycin 1 content	121
Color identity	8
Column chromatography	130
Column chromatographic isomer content	65
Copper content	22
Crystallinity	4
Cycloserine color assay	27
Daunorubicin potency (special turbidimetric)	19
Depressor substance test	40
Disc potency	52
Dissolution test	107
Doxycycline purity (paper chromatography)	130
Free chloride	54
Frozen antibiotic test panel	32
Gas chromatography	32
Gentamicin C	165
Heavy metals test	14
High pressure liquid chromatography (HPLC)	54
Infrared identity	19
Infrared quantitative	19
Iodochlorhydroxyquin content	22
Isoniazid content	22
Karl Fischer moisture	8
LD_{50} toxicity	185
Loss on drying	12
Lysine content	161
Melting range	8
Metal particles (ophthalmic ointments)	22
Microbiological assay, plate	50
Microbiological assay, turbidimetric	29
Microorganism count	68
Nonaqueous titrations (and complexiметric)	22
Paper chromatographic identity	43
Penicillenate and penamaldate content	30
Penicillin chemical assay	15
Penicillin contamination	39
Penicillin G content	32
pH	4
Polarographic assay	33
Potency (special plate)	91
Probenecid content	32
Procaine colorimetric	8
Pyrogens test: 3 rabbits	72
Pyrogens test: 8 rabbits	144
Quantitative thin layer chromatography	80
Residual streptomycin	8
Residue on ignition	26
Solubility identification	54
Specific rotation	22
Specific rotation (potency quantitative)	44
Specific surface area	22

CHARGEABLE FEE PER TEST—Continued

Sterility test	68
Sulfate content	8
Tablet disintegration	5
Thin layer chromatographic identity	43
Total Chlorine	54
Ultraviolet absorptivity	32
Ultraviolet identity	32
Ultraviolet potency	32
Vancomycin identity (bioautograph)	117
Zinc titration	11

(2) The fee for a supplemental request submitted pursuant to the provisions of § 433.12 of this chapter shall be $50.

(3) [Reserved]

(4) In the case of persons using the certification services and whose manufacturing facilities are not located in the United States or the Commonwealth of Puerto Rico, such persons shall be required to deposit each year sufficient funds to cover costs encountered when their facilities are inspected pursuant to the provisions of section 704 of the act.

(c) When the Commissioner considers it necessary to make investigations of a new product containing a certifiable antibiotic drug on which a request has been submitted in accordance with § 431.17, the fee for such service shall be the cost thereof. In such case the request shall be followed by an advance deposit in such amount as the Commissioner specifies, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(d) A person requiring continuing certification services may maintain an advance deposit of the estimated cost of such services for a two-month period. Such deposit shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in the regulations in this chapter unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(e) The fees for the services rendered with respect to each batch certified under the regulations in this chapter shall accompany the request for certification, or the request for check tests and assays, unless such fee is covered by an advance deposit maintained in accordance with paragraph (d) of

this section. Also, if the Commissioner considers that investigations other than examination of such samples are necessary to determine whether or not such batch complies with the requirements of §431.10 for the issuance of a certificate, the fee shall include the cost of such investigations.

(f) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(g) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under §433.12 of this chapter.

(h) All deposits and fees required by the regulations in this chapter, shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health and Human Services, Accounting Branch (HFA–120), 5600 Fishers Lane, Rockville, MD 20857, whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasurer of the United States, for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 40 FR 28052, July 3, 1975; 41 FR 2384, Jan. 16, 1976; 41 FR 18291, May 3, 1976; 44 FR 67113, Nov. 23, 1979; 45 FR 16471, Mar. 14, 1980; 46 FR 16677, Mar. 13, 1981; 46 FR 60578, Dec. 11, 1981; 46 FR 61071, Dec. 15, 1981; 50 FR 19918, May 13, 1985; 55 FR 11582, Mar. 29, 1990]

Subpart C—Records and Reports

§431.61 Records of distribution.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§431.62 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 431, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

Subpart D—Confidentiality of Information

§431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for an antibiotic drug shall be handled in accordance with the provisions established in §314.430 of this chapter.

(c) Notwithstanding the provisions of §314.430 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational antibiotic has been used a copy of any adverse reaction report relating to such use.

[39 FR 44655, Dec. 24, 1974, as amended at 50 FR 7517, Feb. 22, 1985]